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TO: National Institutes of Health DATE: Thursday, January 9, 2020

RE: Response to DRAFT NIH Policy for Data Management and Sharing and Supplemental

DRAFT Guidance

Submitted online at https://osp.od.nih.gov/draft-data-sharing-and-management/

Name: Mary Ellen K. Davis, Executive Director

Name of Organization: Association of College & Research Libraries (ACRL)

Type of Data of Primary Interest: Other

Type of Organization: Professional Org/Association

Role: Institutional Official

Domain of Research Most Important to You or Your Organization (e.g., cognitive neuroscience, infectious diseases, or epidemiology)

The Association of College & Research Libraries (ACRL) is the higher education association for academic libraries and library workers. Representing more than 10,000 individuals and libraries, ACRL (a division of the American Library Association) develops programs, products, and services to help those working in academic and research libraries learn, innovate, and lead within the academic community. Founded in 1940, ACRL is committed to advancing learning, transforming scholarship, and creating diverse and inclusive communities. We enhance the ability of academic library and information professionals to serve the information needs of students and researchers. For example, through a one-day workshop, ACRL presenters travel to campuses across the U.S. and train librarians in the nuances of disciplinary requirements for research data management in order to educate their faculty and students about data best practices. As reflected in our previous support for governmental policies and legislation that facilitate open access and open education—including the NIH Open Access Policy, the Office of Science and Technology Policy mandate, and the Fair Access to Science & Technology Research Act and Federal Research Public Access Act bills— ACRL is fundamentally committed to the open exchange of information to empower individuals and facilitate scientific discovery. On December 5, 2018, ACRL provided comments in response to the NIH Request for Information on Proposed Provisions for a Draft Data Management and Sharing Policy for NIH Funded or Supported Research. We appreciate the revisions NIH made, which address concerns we raised at that time; however, we have the following recommendations for NIH to further improve the policy before its implementation.

DRAFT NIH Policy for Data Management and Sharing

Section I. Purpose (limit: 8000 characters)

We recommend providing a citation to the specific definition of FAIR data principles mentioned at the end of the first paragraph of this section. The following article is cited in the NIH Strategic Plan

Section V. Requirements (limit: 8000 characters)

The timeline for requiring the submission of the Data Management and Sharing Plan should be clarified, particularly in light of Sections IV and VI. Is the Plan to be submitted with the grant application or only upon request (e.g., as Just-In-Time material)?

Section VI. Data Management and Sha@@@revineF32Ff1002@6Tm@g@sterial)?

We appreciate that NIH will allow researchers to update plans "during regular reporting intervals if changes are necessary or at the request of the NIH ICO to reflect changes in the previously documented approach to data management and data sharing throughout the research project, as appropriate."

We recommend NIH more thoroughly explain what is meant by the statement that "Plans will undergo a programmatic assessment" for extramural awards. Include explanations of the evaluation process and criteria.

Section VII. Compliance and Enforcement (limit: 8000 characters)

We appreciate that the Data Management and Sharing Plan review and update process will be integrated into RPPRs. Plans should be a living document that can be adjusted to address the unexpected turns that research can take. This section states that these reviews will happen during regular reporting intervals, with the implication that the same body reviewing RPPRs is reviewing these. NIH should clarify who will be reviewing/assessing plans.

We appreciate that NIH has included compliance language. We recommend making a stronger statement by replacing "may" with "will" in the statement that not following the Plan "may affect future funding decisions." Strengthening the compliance language associated with the policy requiring the public sharing of publications appears to be what significantly improved the compliance rate for that policy.

Similarly, the statement that "A fter the end of the funding period, no-compliance with the NIH ICO-approved Plan may be taken into account" should be strengthened by changing "may" to "will" or should include a more definite statement of what "taken into account" means. (E.g., would reports on past compliance levels be considered as part of any future funding request?)

Supplemental DRAFT Guidance: Allowable Costs for Data Management and Sharing (limit: 8000 characters)

Per the definition of Scientific Data, will digitization costs be allowed in "Curating data and developing supporting documentation"? If so, this should be explicitly stated.

Item 2, Preserving and sharing data through established repositories, allows fees and charges for repositories. However, some repositories require a recurring fee. How will such fees be addressed? Would applicants be granted no-cost extensions (provided the fee is written into the original grant and a specific retention period is defined) to cover these fees beyond the grant period? We recommend NIH develop explicit rules and procedures for how this will work. An alternative to basing repository selection on fee structure may be the development of a funding and budget model that allows for the maintenance and curation of grant-developed resources.

Supplemental DRAFT Guidance: Elements of a NIH Data Management and Sharing Plan (Plan) (limit: 8000 characters)

As data management and sharing is a requirement for responsible research, the word "consider" should be dropped from throughout this section. The Supplementary Information preceding the draft Plan (page 6) states, "...supplemental DRAFT guidance documents intended to help researchers prospectively integrate Data Management and Sharing Plans into routine research practices"

(emphasis added). Again, public access policies for publications succeeded when compliance was enforced.

Throughout this section, remove "consider." Again, data management/sharing is a requirement for good research and as a result of federal funding, NIH research is a public good and thus must be properly managed and shared.

We appreciate that elements of a Plan should provide, "a rationale for decisions about which scientific data are to be preserved." Principal Investigators should thoroughly consider and be able to articulate why they do what their plan says.

Section 1, last bullet. The guidance should explicitly require that human participants are given the option of being made aware of how their data will be shared. This is a core ethical principle.

Section 2. Related Tools, Software, and or/Code. NIH should require sharing of code necessary to reproduce results based on shared data.

Section 5, second bullet. We recommend clarifying the phrasing of "Whether the applicant anticipates entering into any agreements that could limit the ability to broadly share scientific data and describe those agreements." It is unclear what this means or what kind of agreements NIH would allow.

Other considerations relevant to this DRAFT Policy Proposal (limit: 8000 characters) Notes on SUPPLEMENTARY INFORMATION (pages 2-7) provided before the draft Policy.

While page 3 indicates that "Plans will be included as part of the technical evaluation performed by NIH staff," further guidance on evaluation criteria for data management plans will be needed.

Many university libraries provide data management services, such as planning and/or preservation. Researchers that employ such institutional resources should demonstrate that they have made contact with the relevant program managers, for example, through a letter of support.

Page 6 states that "NIH recognizes that the deliberate flexibility of its DRAFT Policy may require additional implementation guidance." We agree that policies require a certain measure of flexibility, especially in a research area as diverse as health. However, flexibility should not be synonymous with weakness. We recommend the entire Supplemental DRAFT Guidance: Elements of a NIH Data Management and Sharing Plan be strengthened by removing the word "consider," thus requiring applicants to provide information for each of the elements described.